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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/580,491	05/30/2000	Kurt Hertogs	TIBO-0016(VIP0004US)	8312

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EXAMINER	
BORIN, MICHAEL L	
ART UNIT	**PAPER NUMBER**
1631	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/580,491	HERTOGS ET AL.	
	Examiner	Art Unit	
	Michael Borin	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 7 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 7 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Amendment filed 03/19/2007 is acknowledged.

Claim 7 is pending.

New matter rejection of record is withdrawn. Therefore, the previously used Condra reference is applied to address the third nucleic acid in claim 7. Further, the rejection under 35 U.S.C. 103(a) is updated to address previously non-elected species of mutations.

Claim Rejections - 35 USC § 103

4. Claim 7 is under 35 U.S.C. 103(a) as being unpatentable over Condra et al. and admitted prior art, and de Bethune (US 6,221,578) and Seki et al. (Antiviral Chemistry & Chemotherapy (1995) 6(2), 73-9), and Bakhanashvili et al (FEBS Letters (1996), 391(3), 257-262).

Condra reference has been used in the prior art rejections throughout preceding prosecution history. The reference addresses issues of resistance of HIV treatment to indinavir, HIV protease inhibitor. The reference evaluates effectiveness of antiviral therapy of HIV patients with protease inhibitor Indinavir (IDV). To evaluate the effectiveness of therapy with IDV, blood of HIV infected patients was collected (same step as step I) of the instant claim), and nucleic acids encoding HIV protease are

examined (i.e., as in step (ii)(c) of claim 7. In one patient, patient "O", at least one mutation, namely 88T (i.e., the elected species) correlates with reduced effectiveness of antiviral therapy (see table 1, patient "O") - the resistance to IDV increased to over 3000 nM (see table 1, column IDV CIC and p. 8270, right col., lines 9-10 from bottom). The thus identified at least one mutation correlates with reduced effectiveness of IDV (which reads on step (iii) of the instant claim.

Note, that even though the instant claim 7, step c), recites various mutations, it is drawn to "at least one" mutation, and, therefore, it reads on situations wherein the recited mutation is one of several others.

Condra et al do not teach address resistance conferred by mutations in HIV reverse transcriptase as it addresses treatment with a protease inhibitor alone.

However as well accepted in the art, and as addressed in the Background section, p. 3, last full paragraph, the preferential HIV therapy includes combination of inhibitors of both PI and RT (reverse transcriptase), the latter can be also a combination of NNTRTI and NRTI. Therefore, it would be obvious to one skilled in the art at the time the invention made to evaluate effectiveness of such combined anti-HIV therapy by determining presence of potential resistance to RT inhibitors.

In regard to the latter, de Bethune et al teach that 101Q mutation in reverse transcriptase (i.e., one of the mutations listed in the instant claim 7 for the first nucleic acid) indicates phenotypical resistance to NNRTI (see Table 9, last line, and col. 18, last paragraph).

Likewise, Larder et al. teaches that 69S-[S-S] mutation (i.e., one of the mutations listed in the instant claim 7 for the second nucleic acid) confers résistance to NRTIs tep (a)(2)).

Further, Bakhanashvili et al (see p. 262, last full paragraph, p. 261, right column, first full paragraph) teach resistance to treatment by nucleoside analogs conferred by Met 184 to Leu mutation in RT, i.e., another mutation addressed in the instant claim 7 with respect to the second nucleic acid.

Taken together, an artisan would be motivated to evaluate effectiveness of anti-HIV therapy by determining presence of potential resistances to both PI and RT inhibitors, i.e., inhibitors used in combination as a part of routine HIV therapy . In the course of assessing potential mutations, an artisan would be motivated to determined to mutations described in Condra, de Bethune, Larder et al. and Bakhanashvili as these mutations are some of the mutations conferring resistance to known HIV PI or RT inhibitors.

With respect to the use of Condra reference, applicant argues, again, that based on the data of table 1, it is unlikely that an artisan would select the particular mutation, 88T mutation, as a marker of effectiveness of anti-HIV therapy. However, the claim uses open-ended language "at least one mutation", which is open for the identification of more than one single mutation, and then using said set of mutations (i.e., "at least one mutation") as markers of effectiveness of anti-HIV therapy. Similarly,

applicant's arguments regarding "single substitution" are not deemed persuasive, as the claims are not directed to a single substitution, but rather to one or more mutations.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. The examiner can normally be reached on 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael Borin, Ph.D.
Primary Examiner
Art Unit 1631

mlb